



सत्यमेव जयते

# The Gujarat Government Gazette

## EXTRAORDINARY

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Separate paging is given to this Part in order that it may be filed as a Separate Compilation.

#### PART IV-B

Rules and Orders (Other than those published in Parts I, I-A, and I-L) made  
by the Government of Gujarat under the Gujarat Acts

#### HEALTH AND FAMILY WELFARE DEPARTMENT

##### NOTIFICATION

Sachivalaya, Gandhinagar, 24<sup>th</sup> December, 2024

#### GUJARAT CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2021.

**No. GHY/34/2024/GOI/132010/13/A:-** WHEREAS in exercise of the powers conferred by sub section (3) of Section 1 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (Guj. 18 of 2021) (herein after referred to as the “said Act”), the Government of Gujarat has appointed the 13<sup>th</sup> September, 2022 on which the said Act has come into force vide Government Notification, Health and Family Welfare Department No. GHY/30/GOI/132010/A, dated the 13<sup>th</sup> September, 2022;

AND WHEREAS it has come to the notice of the State Government that in few of the cases of operations or medical procedures performed by the clinical establishments in which written consent of the patients were obtained but the question which needs to be considered as to whether in such few cases the patients, while giving consent did grant informed consent being fully cognizant of and with clear understanding of the consequences of and likely side effects or possible complications involved in carrying out the operation or the medical procedure as the case may be,

AND WHEREAS, in respect of few procedures which are not emergency procedures, are planned procedures and which result in an outcome which significantly alters patient's life considering possible alternative medical options for the same symptoms or conditions, it is necessary to ensure that while carrying out such operation or such medical procedure by any of the clinical establishment of the State, the patient or patient's relative must be informed and consent thereof must be taken only after thorough explanation to them with regard to the diagnosis, operation, medical procedure, alternative options, possible side effects etc., and to provide a mechanism for structured consent in respect of such procedures;

AND WHEREAS, it has come to the notice of the Government that a few cases of hospital acquired infection have resulted in loss of organ or extended hospitalization for the patient bringing hardship and causing delayed recovery and it is necessary to ensure that all the clinical establishments adhere to the norms of infection control practices as prescribed by the Ministry of Health and Family welfare, Government of India;

AND WHEREAS, it has come to the notice of the Government that a few hospitals are not providing laboratory or diagnostic investigative reports or the diagnosis or prescription made by doctors to the patient upon discharge and to safeguard patients' rights and to enable the patient with having reports for subsequent consultation with any doctor of his/her choice, it is necessary that such reports be provided to the patient as a matter of right upon discharge;

NOW, THEREFORE, in exercise of the powers conferred by Section 43 of the said Act, the Government of Gujarat hereby issues the following directions to all the Clinical Establishments: -

Directions in respect of Informed Consent:

1. It will be mandatory for every clinical establishment of the State to ensure that all the doctors associated with the concerned clinical establishment are properly instructed to seek written informed consent from the patient or the patient's relative before carrying out any operation or procedure invariably.
2. In respect of procedures or surgeries specified in the enclosed Schedule, it would be mandatory to have process of obtaining such informed consent recorded audio visually.
3. While taking every consent, the doctor shall apprise the patient or patient's relative about different medical options in dealing with the situation; potential risks, outcomes and side effects with each treatment option or procedure; chosen or recommended operation or procedure, future planned follow on procedures that have been lined up as part of treatment plan in diseases that require multiple sitting for complete treatment protocol (as in cancer) and any other information that may be relevant in making informed choice before performance of the operation or procedure in the case.
4. After the commencement of the operation or procedure, in case of any new clinical finding as a result of which there needs a change in the operation or procedure as against earlier plan, informed consent of the patient or the patient's relative shall be obtained again by the operating doctor or the team consisting of doctors.
5. It will be mandatory to preserve the audio visual recording for the procedures specified in the Schedule appended below by the clinical establishment for 6 months from the date of operation or the procedure.
6. It is clarified that in case of an emergency where immediate stabilization of a patient is required or where an unattended patient is brought who is not in a position to provide consent then for such cases, treating doctors' decision shall be final and it will not be necessary for him or her to wait for obtaining of informed consent before beginning emergency management and treatment.

Directions in respect of Infection Control Measures:

7. It will be mandatory for every clinical establishment to strictly follow the infection prevention and control guidelines which are issued by the Ministry of Health and Family Welfare, Government of India from time to time. Currently, The National Guidelines For Infection Prevention and Control in Healthcare Facilities issued in January 2020 by the National Centre for Disease Control, MOHFW, Government of India are in operation.

Directions in respect of Providing Copies of Medical Records to the Patient:

8. It will be incumbent upon every clinical establishment to provide a copy of all papers containing investigation report, Radiological Reports, Laboratory reports, Diagnosis and prescription of the doctor etc. to the patient as and when they become available with the hospital and at the time of discharge, without charging any additional fee for the papers.

**SCHEDULE**

<b>Sr. No.</b>	<b>Name of Operation / Procedure</b>
1.	Angiography
2.	Angioplasty
3.	Coronary Artery Bypass Graft
4.	Amputation
5.	Procedure to remove any part of the body (-“ectomy”)
6.	Organ Donation / Organ Transplantation / Organ Retrieval Surgery
7.	Spinal Surgery / Brain Surgery / Cancer Surgery

By order and in the name of the Governor of Gujarat,

**R. A. PRAJAPATI,**

Under Secretary to Government.

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